

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		
Richard M. O'Hara <i>et al.</i>		Attorney Docket No.: WYS-007.01
Serial No:	10/076,934	Confirmation No.: 3689
Filed:	February 15, 2002	Art Unit: 1644
For:	<i>Method for Downmodulating Immune Response in Type I Diabetes</i>	Examiner: I. Ouspenski

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Sir:

Applicants request reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment (“PTA”) indicated in the Notice of Allowance. The Commissioner is authorized to charge the fee required under 37 C.F.R. § 1.18(e), or any other fee required by the filing of this paper, to Deposit Account No. 06-1448, ref. WYS-007.01.

The Notice of Allowance mailed July 16, 2008 indicated a PTA of 137 days. For the reasons given below, Applicants request correction of the PTA to 594 days.

This request for reconsideration is timely because it is filed no later than the payment of the issue fee.

A. Statement of Facts

1. Correct PTA and bases under § 1.702.

The correct PTA is 594 days. The patent is entitled to PTA under 37 C.F.R. §§ 1.702(a)(1) and 1.702(b).

2. Relevant dates as specified in §§ 1.703(a)-(e) and adjustment as specified under 1.703(f).

- a. Application No. 10/076,934 was filed under 35 U.S.C. § 111(a) on February 15, 2002.¹
- b. A Restriction Requirement was mailed on September 3, 2004, which was 507 days after the day that was 14 months after the filing date (i.e., April 15, 2003).
- c. The application had been pending 3 years as of February 15, 2005.
- d. Applicants filed a Request for Continued Examination under 35 U.S.C. § 132(b) on May 18, 2006.
- e. The pendency time after the 3-year period not consumed by continued examination was 457 days, i.e., from February 15, 2005 to May 18, 2006.
- f. The total delay under 37 C.F.R. § 1.702(a)(1) was 507 days, the time period from April 15, 2003 to the mailing of the Restriction Requirement on September 3, 2004.
- g. The total delay under 37 C.F.R. § 1.702(b) was 457 days, the time period from the beginning of three years' pendency on February 15, 2005 to the filing of a request for continued examination on May 18, 2006.
- h. The delays specified in paragraphs (f) and (g) total 964 days.
- i. The adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled is 964 days, less the sum of periods calculated under 37 C.F.R. § 1.704, addressed below.

3. The patent is not subject to a terminal disclaimer.

4. Circumstances constituting failure to engage in reasonable efforts.

- a. Applicants' response to the Notice to File Missing Parts was filed 1 day after the date that was three months after the Notice was mailed.
- b. Applicants' reply under 37 C.F.R. § 1.111 of June 27, 2005 was filed 92 days after the date that was 3 months after the prior action was mailed.
- c. Applicant's first Notice of Appeal of March 15, 2006 was filed 91 days after the date that was 3 months after the final action of September 14, 2005 was mailed.

¹ The application was originally accorded a filing date of 2/19/2002, which was corrected to 2/15/2002 on petition.

d. Applicants' reply under 37 C.F.R. § 1.111 of January 25, 2007 was filed 92 days after the date that was 3 months after the prior action was mailed.

e. Applicant's second Notice of Appeal of September 10, 2007 was filed 94 days after the day that the final action of March 8, 2007 was mailed.

f. Applicant's total delay under 37 C.F.R. § 1.704 was 370 days. The adjustment as specified in 1.703(f) to which the patent is entitled is reduced, therefore, by 370 days.

g. The adjustment as specified in 1.703(f) to which the patent is entitled is 964 - 370 = 594 days.

B. Argument

Applicants request correction of the PTA because the Office delay of 457 days for pendency beyond 3 years (not including time consumed by continued examination) does not overlap any other delay, pursuant to the holding in *Wyeth v. Dudas*, No. 07-1492 (D.D.C. Sept. 30, 2008) ("Memorandum Opinion" and Order) (copy attached to this request as Exhibit A).

In its "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)" published on June 21, 2004, at 69 Fed. Reg. 34238, the Office took the position that "the entire period during which the application was pending before the Office . . . , and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay 'overlap' under 35 U.S.C. § 154(b)(2)(A)." Under this interpretation, the Office delay discussed above in paragraph 2(b) would be considered to "overlap" under 25 U.S.C. § 154(b)(2)(A).

But in a Memorandum Opinion and Order issued on Sep. 30, 2008 in *Wyeth v. Dudas*, Civil Action No. 07-1492, the U.S. District Court for the District of Columbia held that the Office's "Explanation" and "Interpretation" of 35 U.S.C. § 154(b)(2)(A) is invalid because it is inconsistent with the plain text of the statute. The Court held that periods of delay that do not occur on the same calendar days as one another cannot be considered to "overlap," for the simple reason that they do not occur on the same days. The Court dismissed the Office's argument that the 3-year delay begins with the filing of application and instead held that the 3-year delay begins only when the Office has failed to issue a

patent within 3 years of filing, not before. Thus, any delays attributable to the office that occur before the application was pending for 3 years cannot, as a matter of law, be considered overlapping with the delay period that commences at 3 years' pendency.

Under the Court's holding, which is binding on the Office, the Office delay discussed above in paragraph 2(b) (concerning the delay to issuance of the Restriction Requirement) occurred before the 3-year delay period started and so does not overlap with it.

For these reasons, Applicants' patent is entitled to 457 days' adjustment under 37 C.F.R. § 1.702(b) as non-overlapping with the 507 days' adjustment under 37 C.F.R. §§ 1.702(a)(1), for a total adjustment of 964 days less 370 days' delay attributable to Applications, giving a PTA of 594 days under 37 C.F.R. § 1.703(f). Applicants request the issuance or a certificate of correction showing that the PTA is corrected from 137 days to 594 days.

Respectfully submitted,

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Exhibit A**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WYETH, *et al.*, :
: Plaintiffs, :
: v. : Civil Action No. 07-1492 (JR)
: JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
: Defendant. :

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b) (1) (A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b) (1) (A) (i)-(iv). Periods of delay that fit under this provision are called “A delays” or “A periods.” The second provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b) (1) (B). The period that begins after the three-year window has closed is referred to as the “B delay” or the “B period”. (“C delays,” delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b) (1) (b) (i)-(iii), as are periods attributable to the applicant’s own delay. See 35 U.S.C. § 154(b) (2) (C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B) (i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, *et al.*, :
: :
Plaintiffs, :
: :
v. : Civil Action No. 07-1492 (JR)
: :
JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
: :
Defendant. : :

ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge